

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

NOVO NORDISK A/S AND NOVO NORDISK INC.,	§	
	§	CIVIL ACTION NO. 4:23-cv-02246
Plaintiffs,	§	
v.	§	
CHAMPION HEALTH AND WELLNESS CLINICS LLC,	§	
	§	
Defendant.	§	JURY DEMAND
	§	
	§	
	§	

**DEFENDANT CHAMPION HEALTH AND
WELLNESS CLINICS LLC'S ANSWER TO ORIGINAL COMPLAINT**

Defendant Champion Health and Wellness Clinic LLC (“Champion”) hereby submits its Answer, Affirmative Defenses, and Counterclaims to the Original Complaint (“Complaint”) of Plaintiffs Novo Nordisk A/S (“NNAS”) and Novo Nordisk Inc. (“Novo Nordisk”) (collectively “Novo Nordisk” or “Plaintiffs”). Champion denies all allegations in the Complaint not specifically admitted below. Champion reproduces the paragraph headings from AOB’s Complaint. The reproduction of the headings should not be construed as any admission.

Champion answers the numbered paragraphs of the Complaint as follows:

INTRODUCTION

1. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 1 and therefore denies the same.
2. Champion admis that Novo Nordisk offers three prescription-only medicines approved by the FDA, in which semaglutide is the primary ingredient: Wegovy®, Ozempic®, and Rybelsus®. Champion lacks sufficient knowledge or information to form a belief about the

truth of the remaining allegations in Paragraph 2 and therefore denies the same.

3. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 3 and therefore denies the same.

4. Champion admits this action is brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., and related state law claims because it accuses Champions of trademark infringement, false advertising, and unfair competition.

**Novo Nordisk's FDA-Approved Semaglutide Product,
Wegovy®, and Registered Trademark**

5. Champion admits that Plaintiff uses the mark WEGOVY to identify and promote the FDA-approved drug, Wegovy. Champion lacks sufficient knowledge or information to form a belief about the truth of the remaining allegations in Paragraph 5 and therefore denies the same.

6. Admitted.

7. Admitted.

8. Admitted.

9. Admitted.

10. Admitted.

11. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 11 and therefore denies the same.

12. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 12 and therefore denies the same.

**Defendant's Trademark Infringement and False Advertising
in Connection with its sale to patients of unapproved compounded drugs**

13. Defendant admits that it has marketed and prescribed compounded drug products that contain semaglutide. Defendant admits that the FDA does not require compounded drug

products to receive FDA approval.

14. Defendant admits that compounding pharmacies make and provide compounded semaglutide drugs for and to Defendant.

15. Defendant admits that the FDA website defines compounding as a “practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”

16. Defendant admits that the FDA website states that “[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.” Defendant denies that the compounded semaglutide drug it prescribes to patients is unsafe, ineffective, of low quality, or poses any serious health risk to patients. Defendant denies that FDA approval is required in order for Defendant to prescribe compounded semaglutide drugs to patients.

17. Defendant admits that the FDA website states that “Compounded drugs...do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risk. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed.” Defendant denies that the compounded semaglutide drug it prescribes to patients is unsafe, ineffective, of low quality, or poses any serious health risk to patients.

18. Defendant admits that on May 31, 2023, the FDA issued guidance on “medications containing semaglutide marketed for Type 2 diabetes or weight loss,” which provides that: (1) “compounded drugs are not FDA-approved, and the agency does not verify the

safety or effectiveness of compounded drugs”; and (2) “FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality.” Defendant denies that any of its patients have had adverse effects from using compounded semaglutide drugs. Defendant denies that the FDA’s failure to review and approve compounded drugs necessarily means these drugs are unsafe, ineffective, or have risk to patient health.

19. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

20. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the

compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

21. Denied.

22. Denied.

23. Denied.

24. Denied. Defendant has discontinued all use of the WEGOVY mark. Defendant has corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant further denies that it ever offered compounded semaglutide product as Wegovy.

25. Denied. Defendant has discontinued all use of the WEGOVY mark. Defendant has corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug.

26. Admitted.

THE PARTIES

27. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 27 and therefore denies the same.

28. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 28 and therefore denies the same.

29. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 29 and therefore denies the same.

30. Champion admits that it is a Texas limited liability company with a registered agent address at 5900 Balcones Drive, Suite 100, Austin, Texas 78731 and place of business at 4295 San Felipe Street, Suite 335, Houston, TX 77027. Defendant denies that it is currently using the WEGOVY mark in any manner. Defendant further denies that it ever offered compounded semaglutide product as Wegovy.

JURISDICTION AND VENUE

31. Defendant admits that this Court has subject matter jurisdiction over the claims asserted in this case.

32. Defendant admits, for purposes of this action only, that venue is proper in this District and that it is subject to personal jurisdiction in this District.

NOVO NORDISK'S WEGOVY® TRADEMARK

33. Champion admits that U.S. Trademark Registration No. 6,585,492 is purportedly owned by NNAS and purportedly issued on December 14, 2021 for the mark WEGOVY for pharmaceutical preparations in International Class 5. Champion admits that a purported copy of this registration is attached as Exhibit A to the Complaint.

34. Paragraph 34 contains a legal conclusion to which no response is required. To the extent a response is required, Champions denies Paragraph 34.

35. Champion lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 35 and therefore denies the same.

36. Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Champions denies Paragraph 36.

37. Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Champions denies Paragraph 37.

DEFENDANT'S ALLEGEDLY INFRINGING USE OF THE WEGOVY® MARK

38. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®. Defendant admits that Exhibit B contains examples of Defendant's past marketing materials.

39. Denied. The advertisements referenced in Paragraph 39 are no longer active or available.

40. Denied. The advertisements referenced in Paragraph 40 are no longer active or available.

41. Denied. Defendant no longer uses the WEGOVY mark in any advertising materials.

42. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the

compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

43. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

44. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

FIRST CAUSE OF ACTION
(Alleged Trademark Infringement in Violation of 15 U.S.C. § 1114(1))

45. Defendant incorporates its responses to each of the foregoing allegations.

46. Paragraph 46 contains a legal conclusion to which no response is required. To the extent a response is required, Defendant denies Paragraph 46.

47. Paragraph 47 contains a legal conclusion to which no response is required. To the extent a response is required, Defendant denies Paragraph 47.

48. Paragraph 46 contains a legal conclusion to which no response is required. To the extent a response is required, Defendant denies Paragraph 46.

49. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

50. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to

insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

51. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Defendant denies that Plaintiffs have been or will be irreparably harmed but has agreed to permanently cease and desist from using the WEGOVY mark and does not oppose

entry of a preliminary and permanent injunction.

57. Denied.

58. Denied.

SECOND CAUSE OF ACTION

(Alleged Trademark Infringement, Use of False Designation of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A))

59. Champion incorporates its responses to each of the foregoing allegations.

60. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

61. Denied. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was

made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

62. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®.

Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Defendant denies that Plaintiffs have been or will be irreparably harmed but has agreed to permanently cease and desist from using the WEGOVY mark and will not oppose entry of a preliminary and permanent injunction.

68. Denied.

69. Denied.

THIRD CLAIM FOR RELIEF

**(Defendant's Alleged False and Misleading Advertising and Promotion
in Violation of 15 U.S.C. §1125(a)(1)(B))**

70. Champion incorporates its responses to each of the foregoing allegations.

71. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

72. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

73. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

74. Denied. Defendant has removed all references to WEGOVY from its marketing materials.

75. Denied. Defendant has removed all references to WEGOVY from its marketing materials.

76. Denied.

77. Denied.

78. Denied.

79. Defendant denies that Plaintiffs have been or will be irreparably harmed but has agreed to permanently cease and desist from using the WEGOVY mark and will not oppose entry of a preliminary and permanent injunction.

FOURTH CAUSE OF ACTION
(Common Law Unfair Competition)

80. Champion incorporates its responses to each of the foregoing allegations.

81. Defendant admits that it has prescribed compounded semaglutide drugs to its

patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Defendant denies that Plaintiffs have been or will be irreparably harmed but has agreed to permanently cease and desist from using the WEGOVY mark and will not oppose entry of a preliminary and permanent injunction.

FIFTH CAUSE OF ACTION
(Common Law Trademark Infringement)

87. Champion incorporates its responses to each of the foregoing allegations.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent a response is required, Paragraph 88 is denied.

89. Defendant admits that it has prescribed compounded semaglutide drugs to its patients. Defendant admits that it innocently used the WEGOVY mark on its website from June 2022 to June 2023, but was ultimately unable to prescribe Wegovy to patients due to insurance

coverage issues. Defendant has since corrected the advertising on its website to clarify that it only offers a compounded semaglutide drug. Defendant denies that it ever marketed the compounded semaglutide drug to patients as the brand name drug Wegovy® in any direct communications with patients. Each patient who received the compounded semaglutide drug was made aware that the drug they were receiving was not the brand name drug Wegovy®. Defendant denies that it ever attempted to pass off the compounded semaglutide drug to patients as the brand name drug Wegovy®.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Defendant denies that Plaintiffs have been or will be irreparably harmed but has agreed to permanently cease and desist from using the WEGOVY mark and will not oppose entry of a preliminary and permanent injunction.

PRAYER FOR RELIEF

This section constitutes a prayer for relief that does not require a response. To the extent a response is required, Champion admits the Court should enter an Order declaring that from June 2022 to June 2023, Champion infringed the WEGOVY marks under 15 U.S.C. § 1114 and 1125(a)(1)(A) and engaged in common law trademark infringement and unfair competition, and permanently enjoin CHAMPION and each of its officers, agents, servants, employees, parents, subsidiaries, affiliates, and those acting in active concert or participation with them from

infringing the WEGOVY marks. Champion denies that any infringement or other conduct was intentional or willful. The remaining allegations in the Prayer for Relief are denied.

JURY DEMAND

Champions requests a jury trial on all issues triable by jury.

CHAMPION'S AFFIRMATIVE DEFENSES

Champion asserts the following defenses and affirmative defenses, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden of proof when such burden would otherwise be on Plaintiff. Champion reserves the right to further amend this Answer with additional defenses and affirmative defenses as discovery commences and progresses in this suit. Champion reserves all defenses and affirmative defenses permitted under the Federal Rules of Civil Procedure, the laws of the United States, and/or at law or in equity, that may now exist, that may exist in the future, or that are presently known or later discovered through further investigation in this suit.

First Defense
(Limitation on Damages)

Plaintiffs' damages, if any, are limited to the time period from June 2022 to June 2023.

Second Defense
(No willfulness)

Plaintiff's alleged infringement was not willful or intentional, and thus, Defendants are not entitled to any enhanced or treble damages.

DEMAND FOR JURY TRIAL

Champion demands a trial by jury on all issues so triable.

Dated: July 13, 2023

Respectfully submitted,

/s/ J. David Cabello

J. David Cabello

Attorney-in-Charge

Texas Bar No. 03574500

Munira A. Jesani

Texas Bar No. 24101967

Telephone: (832) 631-9992

Facsimile: (832) 631-9991

David@CHZFirm.com

CABELLO HALL ZINDA, PLLC

801 Travis Street, Suite 1610

Houston, TX 77002

**ATTORNEY FOR CHAMPION
HEALTH AND WELLNESS CLINICS
LLC**

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 13th day of July 2023, a true and correct copy of the above was electronically filed with the Clerk of Court using the CM/ECF system, which sends notifications of such filing to all counsel of record who have consented to accept service by electronic means.

/s/ John Watkins

John Watkins

Paralegal